REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

Claims 4-8, 17, 79, 80, 89-99, 101, 107, 111-115, 121-123, and 126-137 are currently withdrawn from examination. Claims 1, 3, 11 and 120 are being amended. Upon entry of these revisions, claims 1-18 and 79-137 will be pending.

I. Rejection under 35 USC §112, First Paragraph

A. The examiner's rejection for alleged lack of written-description should be withdrawn because the specification shows the inventors' possession of the invention at the time of filing

Claims 1-3, 9-16, 18, 81-88, 100, 102-106, 108-110, 116-120, 124, and 125 are rejected for failing to comply with the written description requirement. The examiner argues that the broad scope of the claimed subject matter is not adequately supported by the present specification. In particular, the examiner argues that the claimed GPI "derivatives or equivalents," are not described in such as way to allow "the skilled artisan to envision all the contemplated substances." Applicants respectfully disagree.

The specification discloses multiple structural formulas, which teach the essential portions of the molecule as well as identify the areas available for modification and the extent of the modifications that can be made without disrupting the function of the molecule. Specification pages 16-20. Additionally, the specification teaches several functional assays such as Example 12 on page 69, Example 13 starting on page 69, Example 14 on page 70, and Example 18 on page 72. Enlightened by the structural information, embodied in the formulas, and by the functional information, reflected in the assay results of the specification, the skilled person could readily envision the molecules encompassed by the present claims.

Accordingly, applicants' specification provides a clear indication that applicants, at the time their application was filed, possessed the claimed invention.

B. The examiner's rejection for alleged lack of enablement should be withdrawn because the specification enables the skilled artisan to make and/or use the invention

Claims 1-3, 9-16, 18, 81-88, 100, 102-106, 108-110, 116-120, 124, and 125 are rejected for containing subject matter that is not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Again, the examiner's contention lies with the alleged breadth of the subject matter claimed. In this instance, the examiner argues that the specification does not describe how to practice the claimed methods, i.e., how to treat or prevent any mammalian disease or condition with the "derivations or the equivalents of GPI." Applicants respectfully disagree.

As explained above, a skilled artisan can identify the functional "derivatives or equivalents" for use in the treatment of prevention of mammalian diseases by using the formulas and functional assays taught in the specification. Furthermore, the specification in Example 22 on page 75, describes the use of a mouse model to determine GPI's treatment effectiveness with regards to malaria sporozites. Therefore, one of skill in the art can easily identify, from the information provided in the specification, a functional GPI "derivative or equivalent" and treat or prevent a mammalian disease, as taught in the mouse model of Example 22.

Additionally, applicants argue that the examiner is mistaken in her application of the Schofield et al. (2002) publication, which the examiner cited as teaching that GPI was not effective in provoking an immune response. Even if this were true, it is irrelevant for the present claims, because the present invention claims that GPI may be used to activate helper T cells, i.e. invoke an antibody response. Schofield et al. (2002) clearly supports GPI activation of helper T cells because GPI was shown to prevent pulmonary oedema, acidosis and cerebral malaria through the GPI induced production of antibodies. See Schofield et al, page 787 Figure 2 and page 788, column 1. Therefore, applicants argue that this reference, in

fact, supports that no undue experimentation is required to use the present invention, *i.e.*, to use GPI derivative or equivalents to activate helper T-cells.

II. Rejection under 35 USC §112, Second Paragraph

Claims 3, and 11-16 are rejected as being indefinite for failing to distinctly claim the subject matter of the invention. As requested by the examiner, applicants have amended claims 3 and 11. Applicants believe that the present claims satisfy 35 USC §112, second paragraph, and request that the examiner withdrawn this rejection.

III. Rejection under 35 USC §102(a), §102(b) and §103(a)

A. The examiner's rejection under 102(b) should be withdrawn because the Schofield reference does not anticipate the present invention

Claims 1-3, 9-18, 81-88, 100, 102-106, 108, 109, 116-120, 124. and 125 stand rejected as anticipated by Schofield et al. (1993), interpreted in light of Nagata et al. (1993). The examiner alleges that Schofield teaches the administration of GPI or GPI analogs in vivo, for production of anti-GPI antibodies in the treatment of malaria.

The Schofield reference actually teaches that GPI is a toxin of malaria parasites and acts as a thymus-independent antigen, eliciting responses from B-cells without T cell help. In contrast, the present application teaches that the administration of GPI activates helper T cells, which then elicits the antibody response useful for treatment and prevention of mammalian diseases. Additionally, applicants believe that the Schofield reference teaches away from administering GPI to treat mammalian diseases because all of the mice injected with the GPI toxin died. Accordingly, a skilled artisan would not administer GPI to activate helper T cells.

B. The examiner's rejection under 35 USC §102(a) and §103(a) should be withdrawn because the applications priority date is October 28, 1998

The examiner has rejected claims 11-13, 86-88 and 116-188 under 102(a) as anticipated by Schofield et al (1999), read in view of van Joost et al (1992) and Paul (1989), and separately by WO 99/52547. Additionally, the examiner rejected claims 11-13, 86-88 and 116-188 under 103(a) over the combination of WO 99/52547 (1999), Tachado et al., and Joyce et al. Applicants argue that these rejections should be withdrawn because the appropriate priority date for claims 11-13, 86-88 and 116-188 is October 28, 1998. The 1998 date is the proper priority date because the specific GPI molecules covered by the present claims were taught in the provisional application's description of GPI genus as a whole. Accordingly, applicants request that the examiner reconsider and withdraw these rejections.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 24 January 2005 By S. A. Bent

FOLEY & LARDNER LLP
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768